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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/480,850	06/07/95	PELLETT F	1414.657

18M1/0203

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EXAMINER	
LEE,D	

ART UNIT	PAPER NUMBER
1815	

DATE MAILED: 02/03/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/480,850	Applicant(s) Philip E. Pellett
	Examiner Danny Lee	Group Art Unit 1815

☒ Responsive to communication(s) filed on *Oct 31, 1997*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *7, 8, and 16-21* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *7, 8, and 16-21* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Receipt is acknowledged of applicants' amendment after final in Paper No. 17, filed 10/31/97, wherein claim 16 is amended and new claims 17-21 are presented. Accordingly, claims 7-8, 16-21 are under consideration in the present application.

2. Claims 7-8, 16-21 are rejected under 35 U.S.C. § 103 as being unpatentable over Lee et al. (AA1) or Lee et al. (AW) in view of Luckow et al. (AO), Matsuura et al (AP) and further in view of Krishna et al (J. Gen. Virology, 1989).

Lee et al. (AW) teaches a pure HSV gG-1 antigen immunoaffinity purified by mouse monoclonal H1379-2 antibodies(see page 112, second full paragraph).

Lee et al. (AA1) teaches a pure HSV gG-2 antigen immunoaffinity purified by mouse monoclonal H966 antibodies (see page 641,second column, last paragraph, page 642, first column, first full paragraph and page 643, first column, fourth full paragraph). Lee et al. (AA1) and Lee et al. (AW) do not disclose the production of gG-1 or gG-2 in a baculovirus expression system.

Luckow et al. discloses the development of baculovirus expressions systems and the advantages of using such systems for "the very abundant expression of recombinant proteins, which are in many cases, antigenically, immunologically, and functionally similar to their authentic counterparts" (see page 47, first column, first full paragraph). Luckow et al. also discloses many of the vectors suitable for baculovirus expression systems and the importance of particular leader sequences upstream from the polyhedron gene ATG and their impact on protein production (see page 51, first column, last paragraph).

Similarly, Matsuura et al. also discloses the uses and advantages of the baculovirus expression system and teaches "that the immediate 5' upstream sequences are important for high level expression" (see page 1234, Figure 1 and see page 1247, second full paragraph). Matsuura et al, also discloses vector pAcRP18 which has the "5' nontranslated leader sequence of the polyhedron gene joined to the coding region of a foreign gene precisely at the translation initiation codon of the polyhedron gen" of the claimed inventions. Neither Luckow et al. or Matsuura et al. teach the expression of gG-1 or gG-2 peptides in baculovirus expression systems. However, the level of ordinary skill in the genetic engineering art is exceptionally high and, absent convincing objective evidence to the contrary, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to express the gG-2 protein of Lee et al. (AA1) or the gG-1 protein of Lee et al. (AW) in the baculovirus expression system of Luckow et

al. or Matsuura et al. for the expected benefit of obtaining high levels of expression of gG-1 and gG-2 proteins.

Krishna et al teaches the expression of gD in baculovirus (abstract).

One of ordinary skill in the art would have been motivated to express the proteins in a baculovirus system since Luckow et al. and Matsuura et al. disclose the numerous advantages of baculovirus expressions systems, the importance of retaining an intact 5' nontranslated leader sequence of the polyhedron gene and one of ordinary skill would have had a reasonable expectation of success since Luckow et al. and Matsuura et al. both establish that the baculovirus system produces significant amounts of peptides and that such peptides "are in many cases, antigenically, immunologically, and functionally similar to their authentic counterparts." One would have a high expectation of success as taught by Krishna.

Applicant's arguments have been considered are not deemed persuasive. Applicant argues that the novel plasmid pAcDSM, is engineered to receive the foreign gene precisely at the translation initiation codon of the polyhedron gene, without missing any nucleotide present in the native 5' nontranslated leader sequence is noted, but these limitations are not in the claims. **The claims are drawn to a purified herpes simplex virus gG1 and/or gG-2 antigens and not toward the baculoviral expression system**. Applicant's claims constitute a product-by-process type claims and the burden is upon applicant to demonstrate the distinction between the material, structural and functional characteristics of the claimed composition and the compositions of the prior art. Applicant argues that the protein made by the expression system of Sanchez-Martinez and Pellett, may differ from the art because of the differences of the transfer vector.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., minimal cross reactivity) are not recited in the rejected claim(s). Although the claims are interpreted in light of

the specification, limitations from the specification are not read into the claims. *In re Van Guens*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Figure 2 of the Martinez et al (Virology, 1991) disclose a comparison between the claimed vector (AcDSMgG1) and a different baculoviral vector (Ac373'gG1). Applicants are requested to provide evidence and arguments between the claimed vector (AcDSMgG1) and a different baculoviral vector (Ac373'gG1).

Applicant argues that the novel plasmid pAcDSM, is engineered to receive the foreign gene precisely at the translation initiation codon of the polyhedron gene, without missing any nucleotide present in the native 5' nontranslated leader sequence is noted. Applicant's argument is not supported by the as-filed specification or evidence. Claim 16, 18-21 are drawn toward a purified herpes simplex virus gG1 and/or gG-2 antigens and not toward the specifics of the baculoviral expression system. Applicant's claims constitute a product-by-process type claims and the burden is upon applicant to demonstrate the patentable distinction between the material, structural and functional characteristics of the claimed composition and the compositions of the prior art. In conclusion, applicant have not provided any evidence to the contrary wether the proteins of the prior art are different or may in fact be the same proteins as those claimed by applicant.

More ever, the selection of a particular transfer vector is deemed to be a result-effective parameter routinely optimized by the artisan of ordinary skill as taught by Matsuura and Luckow. Thus, the transfer vector disclosed in the specification is deemed obvious under 35 U.S.C. §103.

In conclusion, applicants (product-by-process) recombinant proteins is made obvious by the Lee et al (1985), Lee et al (1986), Matsuura and Luckow. Applicant has failed to provide convincing evidence and arguments to support a patentable distinction between the proteins of the prior art and those claimed by applicants. Applicant is requested to submit evidence to show the distinction of the claimed gG1 and gG2 proteins and those of the prior art (a different baculoviral expression system). How is the baculoviral vector of the instant invention contribute to unobvious distinction of the glycoprotein over the glycoprotein of the prior art (both Lee et al in view of Matsuura)?, How is the glycosylation pattern altered? , How is the methylation pattern?, post translational modification of the gG proteins and its eventual effect on the antigenicity the glycoprotein or its immune and/or diagnostic alteration that will allow it to be better recognized over the glycoprotein of the prior art.

No claims are allowed.

Papers relating to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 located in Crystal Mall 1. The Fax number for Art Unit 1813 is (703) 305-7939. All Group 1800 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Danny Lee whose telephone number is (703) 305-7245. The Examiner can normally be reached on Monday-Tuesday from 8:00 AM-6:30 PM, (EST)and Thursday-Friday from 8:00 AM-6:30 PM (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marian Knode, can be reached at (703) 308-4311.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Danny Lee
February 2, 1998

Marian C. Knode

MARIAN C. KNODE
SUPERVISORY PATENT EXAMINER
GROUP 1800